K091816

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SECTION 5
510(k) SUMMARY

510(k) SUMMARY

1. Submitter:

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752
Telephone: 508-683-4560
Fax: 508-683-5939

Contact: Janis F. Taranto, M.S., RAC
Regulatory Affairs Specialist
Date Prepared: June 16, 2009

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2. Proposed Device:

Trade Name: Ultraflex™ Esophageal NG Stent System
Classification Name: Esophageal Prosthesis
Regulation Number: 878.3610
Product Code: ESW
Classification: Class II

3. Predicate Device:

Trade Name: Ultraflex™ Esophageal NG Stent System
Manufacturer and Clearance Number: Boston Scientific Corporation, K032930
Classification Name: Esophageal Prosthesis
Regulation Number: 878.3610
Product Code: ESW
Classification: Class II

4. Proposed Device Description:

The proposed Ultraflex Esophageal NG Stent System allows for the placement of a self-expanding metallic stent within the esophagus. The systems consist of a flexible delivery catheter preloaded with an expandable stent. The stent is offered either bare or covered and with either a proximal release or distal release delivery system. The stent may be placed fluoroscopically using radiopaque markers as a guide or endoscopically using the visual marker on the delivery catheter. The proposed device also incorporates two adhesive material changes and the addition of a visual marker on two models.

5. Intended Use:

Ultraflex™ Esophageal NG Stent System (non-covered) is intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors only.

Ultraflex™ Esophageal NG Stent System (covered) is intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors only, and occlusion of concurrent esophageal fistula.

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6. Technological Characteristics:
The proposed Ultraflex™ Esophageal NG Stent System is nearly identical in design, materials, and manufacturing processes to the predicate Ultraflex™ Esophageal NG Stent System (K032930).

7. Performance Data:
In-vitro testing has been performed and all components, subassemblies, and/or full devices met the required specifications for the completed tests.

8. Conclusion:
Boston Scientific Corporation has demonstrated that the proposed Ultraflex™ Esophageal NG Stent System is substantially equivalent to Boston Scientific Corporation's currently marketed Ultraflex™ Esophageal NG Stent System (K032930).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 1 2009

Ms. Janis Taranto
Regulatory Affairs Specialist
Boston Scientific Corporation
Endoscopy Division
100 Boston Scientific Way
MARLBOROUGH MA 01752

Re: K091816
Trade/Device Name: Ultraflex™ Esophageal NG Stent System (non-covered)
Ultraflex™ Esophageal NG Stent System (covered)
Regulation Number: 21 CFR §878.3610
Regulation Name: Esophageal prosthesis
Regulatory Class: II
Product Code: ESW
Dated: June 16, 2009
Received: June 18, 2009

Dear Ms. Taranto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K091816

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SECTION 4
INDICATIONS FOR USE STATEMENT

510(k) Number (if known): ~~To Be Determined~~ K091816

Device Name: Ultraflex™ Esophageal NG Stent System

Indications for Use: Ultraflex™ Esophageal NG Stent System (non-covered) is intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors only.

Ultraflex™ Esophageal NG Stent System (covered) is intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors only, and occlusion of concurrent esophageal fistula.

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Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K091816